



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5225]

Agency Information Collection Activities; Proposed Collection; Comment Request;

Foreign Supplier Verification Programs for Food Importers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements associated with our Foreign Supplier Verification Programs for Food Importers.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-5225 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Foreign Supplier Verification Programs for Food Importers." Received comments, those filed in a timely

manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Foreign Supplier Verification Programs (FSVP) for Food Importers--21 CFR Part 1, Subpart L

OMB Control Number 0910-0752--Extension

This information collection supports FDA regulations in 21 CFR part 1, subpart L (21 CFR 1.500 through 1.514), which help to implement section 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a). Section 805 authorizes the Agency’s FSVP and

establishes requirements applicable to imported food. Respondents to the information collection are importers, as defined in section 805(a)(1) of the FD&C Act. The regulations are intended to provide verification that imported food is produced in compliance with statutory requirements that include the implementation of appropriate risk-based preventive controls. The regulations also establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions. To assist respondents with understanding the requirements we have developed Agency guidance, available at: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals>.

Specifically, regulations in 21 CFR 1.501 set forth the applicability of requirements for FSVP, while regulations in sections 1.502 through 1.508, prescribe specific activities for developing, maintaining, and following an FSVP; as well as for evaluating compliance and for identifying and correcting hazards. Finally, regulations in section 1.509 identify required data elements applicable to food products offered for importation into the United States, while regulations in 1.510 govern required records, providing that records be made available to FDA upon request and that records be maintained electronically. On May 10, 2021, FDA launched the FSVP Importer Portal for FSVP Records Submission as a means for importers to upload FSVP records electronically and submit them to the Agency, after receiving a request for records from

FDA. The portal may be found at <https://www.access.fda.gov/>, and a user guide is available at <https://www.fda.gov/media/148312/download>.

We estimate the burden for the information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Exemption for food for research; 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
Identifier for filing with U.S. Customs and Border Protection; 1.509	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total			10,372,000		299,067

¹ There are no capital costs or operating and maintenance costs associated with the information collection.

Table 2.--Estimated Annual Recordkeeping Burden^{1,2}

Information Collection Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Controls for low-acid canned foods; 1.502(b)	2,443	4	9,772	1	9,772
Hazard determinations, controls, and audits; 1.504, 1.506, 1.511	56,800	87.74	4,984,036	0.38 (23 minutes)	1,917,174
Written assurances for food produced under dietary supplement current good manufacturing practices; 1.511	11,701	2.88	33,664	2.25	75,744
Document very small importer/certain small foreign supplier status; 1.512(b)(1)	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier; 1.512(b)(3)	50,450	2.79	141,084	2.25	317,439
Total			5,219,006		2,370,579

¹ There are no capital costs or operating and maintenance costs associated with the information collection.

² Figures have been rounded to the nearest one hundredth.

Upon evaluation of the information collection, we are retaining the currently approved burden estimates.

Dated: January 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

